D5687

(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1276 Standard: Clinical cytogenetics

(d) The laboratory report must include a summary and interpretation of the observations, number of cells counted and analyzed, and use the International System for Human Cytogenetic Nomenclature.

Probes §493.1276(d)

Does the laboratory report include:

- Type of banding method used, if applicable;

- Stage of cell mitosis when banded;

- Number of cells counted and analyzed microscopically;
- Number of cells from which photographic or computerized karyotypes were prepared; and

- Estimate of the banding resolution achieved?

Does the laboratory, where appropriate, ensure that FISH clinical interpretations are made in conjunction with standard cytogenetic analyses and evaluated against patient medical history and other diagnostic test results?

Preliminary reports of karyotypes based on less than full analysis are acceptable if the diagnosis is clear.

For what types of cultures are preliminary reports issued? These may include, but are not limited to, the following:

- Bone marrow analysis (within 14 days);

- Unstimulated blood cultures (within 14 days); and

- Lymphocytes from newborns (within 7 days).

What is the **average** length of time for reporting (use D5801or D5815, as appropriate):

- Amniotic fluid cell cultures (90% of prenatal diagnosis cases should be signed out in 21 days);

- Routine lymphocyte cultures (approximately 4-5 weeks); and

- Fibroblast cultures (approximately 2-3 months)?

Do records document:

- Observations made concurrently with the performance of each step in the examination of specimens/cultures (use D5683); and

- The number of cases reviewed, signed out and/or the frequency of failed or sub-optimal cultures?

§493.1276 Standard: Clinical cytogenetics

(e) The laboratory must document all control procedures performed, as specified in this section.

Probes §493.1276(e)

Each day of use, does the laboratory test the positive and negative reactivity of staining materials to ensure predictable staining characteristics? Use D5473.

Does the laboratory, concurrent with the initial use, check each batch of media for pH (amniotic cell cultures should be kept between pH 6.8 and 7.8), sterility, and ability to support growth? Use D5477.

Does the laboratory employ an alternative procedure for the immediate assessment and monitoring of all testing over time? For example: Control materials are not routinely available to demonstrate chromosome abnormalities for linkage, breakage or translocation, but the laboratory must demonstrate an alternative mechanism for detecting chromosome abnormalities to be analyzed. Use D5485.

An alternative procedure might include spit sample with another laboratory, repeat patient specimen, special stains, FISH assays, and/or molecular assays.

§493.1278 Standard: Histocompatibility

(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

(a) General. The laboratory must meet the following requirements.

Interpretive Guidelines §493.1278(a):

When condition-level deficiencies in Histocompatibility are identified in any or all phases of testing, cite D5042.